provided for under paragraph (d) of this section.

(d) *Over-the-counter (OTC) drugs.* Over-the-counter drug products, other than those which in normal use may be applied to mucous membranes or which are intended to be used on mucous membranes, may contain hexachlorophene only as part of an effective preservative system, at a level that is no higher than necessary to achieve the intended preservative function, and in no event higher than 0.1 percent. Such use of hexachlorophene shall be limited to situations where an alternative preservative has not yet been shown to be as effective or where adequate integrity and stability data for the reformulated product are not yet available. This use of hexachlorophene will not, by itself, require an approved new drug application. Use of hexachlorophene as a preservative at a level higher than 0.1 percent is regarded as a new drug use requiring an approved new drug application, which must be submitted within the time set out in paragraph (c)(4) of this section.

(e) *Cosmetics.* Hexachlorophene may be used as a preservative in cosmetic products other than those which in normal use may be applied to mucous membranes or which are intended to be used on mucous membranes, at a level that is no higher than necessary to achieve the intended preservative function, and in no event higher than 0.1 percent. Such use of hexachlorophene shall be limited to situations where an alternative preservative has not yet been shown to be as effective or where adequate integrity and stability data for the reformulated product are not yet available. The component of a preservative system whether hexachlorophene or other antimicrobial agent, should be selected on the basis of the effect on the total microbial ecology of the product, not merely on gram-positive bacteria.

(1) Adequate safety data do not presently exist to justify wider use of hexachlorophene in cosmetics.

(2) Antibacterial ingredients used as substitutes for hexachlorophene in cosmetic products, and finished cosmetic products containing such ingredients, shall be adequately tested for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing may be adulterated and will in any event be deemed misbranded unless it contains a conspicuous front panel statement that the product has not been adequately tested for safety and may be hazardous.

(f) *Content statement.* All reference to hexachlorophene limit in this order is on a weight-in-weight (w/w) basis. Quantitative declaration of hexachlorophene content on the labeling of the products, where required, shall be on a w/w basis.

(g) *Shipments of products.* Shipments of products falling within the scope of paragraphs (c), (d), or (e) of this section which are not in compliance with the guidelines stated herein shall be the subject of regulatory proceedings after the effective date of the final order.

(h) *Prior notices.* This order preempts any conditions for marketing products set forth in the following prior notices.

1. DESI No. 4749 (34 FR 15389, October 2, 1969), ''Certain OTC Drugs for Topical Use.''
2. DESI No. 2855 (35 FR 12423, August 4, 1970), ''Certain Mouthwash and Gargle Preparations.''
3. DESI No. 8940 (36 FR 14510, August 6, 1971), ''Topical Cream Containing Pyrilamine Maleate, Benzocaine, Hexachlorophene, and Cetrimonium Bromide.''
4. DESI No. 6615 (36 FR 18022, September 8, 1971), ''Deodorant/Antiperspirant.''
5. DESI No. 6270 (36 FR 23330, December 8, 1971), ''Certain Preparations Containing Hexachlorophene''.

[40 FR 14033, Mar. 27, 1975, as amended at 42 FR 63773, Dec. 20, 1977; 55 FR 11577, Mar. 29, 1990; 67 FR 4906, Feb. 1, 2002; 69 FR 18763, Apr. 8, 2004]

PART 290—CONTROLLED DRUGS

Subpart A—General Provisions

Sec.

Subpart B [Reserved]

Subpart C—Requirements for Specific Controlled Drugs [Reserved]

AUTHORITY: 21 U.S.C. 352, 353, 355, 371.

SOURCE: 40 FR 14040, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 290.1 Controlled substances.

Any drug that is a controlled substance listed in schedule II, III, IV, or V of the Federal Controlled Substances Act or implementing regulations must be dispensed by prescription only as required by section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act unless specifically exempted in § 290.2.

[67 FR 4906, Feb. 1, 2002]

§ 290.2 Exemption from prescription requirements.

The prescription-dispensing requirements of section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act are not necessary for the protection of the public health with respect to a compound, mixture, or preparation containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams that also includes one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by codeine alone.

[67 FR 4907, Feb. 1, 2002]

§ 290.5 Drugs; statement of required warning.

The label of any drug listed as a ''controlled substance'' in schedule II, III, or IV of the Federal Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning: ''Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.'' This statement is not required to appear on the label of a controlled substance dispensed for use in clinical investigations which are ''blind.''

§ 290.6 Spanish-language version of required warning.

By direction of section 305(c) of the Federal Controlled Substances Act, § 290.5, promulgated under section 503(b) of the Federal Food, Drug, and Cosmetic Act, requires the following warning on the label of certain drugs when dispensed to or for a patient: ''Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.'' The Spanish version of this is: ''Precaucion: La ley Federal prohibe el transferir de esta droga a otra persona que no sea el paciente para quien fue recetada.''

§ 290.10 Definition of emergency situation.

For the purposes of authorizing an oral prescription of a controlled substance listed in schedule II of the Federal Controlled Substances Act, the term *emergency situation* means those situations in which the prescribing practitioner determines:

(a) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and

(b) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under schedule II of the Act, and

(c) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

Subpart B [Reserved]

Subpart C—Requirements for Specific Controlled Drugs [Reserved]

PART 299—DRUGS; OFFICIAL NAMES AND ESTABLISHED NAMES

Subpart A—General Provisions

Sec.

AUTHORITY: 21 U.S.C. 331, 351, 352, 355, 358, 360b, 371.

SOURCE: 40 FR 14041, Mar. 27, 1975, unless otherwise noted.